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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,624

10/13/2005

Jesper Mortensen Haaning

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69987 7590 10/13/2010

BAYER HEALTHCARE LLC

Law & Patents

800 Dwight Way

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

10/13/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,624	Applicant(s) HAANING ET AL.	
	Examiner HOPE A. ROBINSON	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,13,14,25-28,30,32,35,50,51,53-55,62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 51,53,54,62 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,13,14,25-28,30,32,35,50 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/25/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed January 26, 2010 on July 28, 2010 is acknowledged.

Claim Disposition

2. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50-51, 53-55 and 62-63 are pending.
Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are under examination.
Claims 51, 53-54 and 62-63 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Maintained-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to an isolated or recombinant FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of human FVII or FVIIa (SEQ ID NO:1), in no more than 15 amino acid residues and wherein the structure has the modification of L65Q. The claims can be construed as open, based on the open language "comprising", thus the recited "in no more than 15 amino acid residues" is not limited to 15 modifications. With the recited modification at position L65Q, claim 1 can be construed as having at least 16 modifications. Note also that dependent claim 2 recites 18 modifications (see also claim 35 with 30 modifications). Therefore, the claimed invention contemplates more than 15 modifications.

In addition, the instant specification does not provide support for the aforementioned amendatory language. At paragraph [0083] the specification discloses that, "A 'variant' is a polypeptide, which differs in one or more amino acid residues from its parent polypeptide, normally in 1-15 amino acid residues (e.g. in 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15 amino acid residues), such as in 1-10 amino acid residues, e.g. in 1-8, 1-6, 1-5 or 1-3 amino acid residues. Normally, the parent polypeptide is hFVII or hFVIIa. Thus, a 'variant' typically contains 1-15 amino acid modifications (for

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example 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15 amino acid modifications), such as 1-10 amino acid modifications, e.g. 1-8, 1-6, 1-5 or 1-3 amino acid modifications relative to the parent polypeptide". Clearly the invention is drawn to a genus of structures not adequately described.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Moreover, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure

of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Response to Arguments

4. The response filed by applicant has been considered in full. Withdrawn rejections will not be discussed herein as applicant's comments are moot. Note that the rejection under 35 USC 112, first paragraph remains. Applicant aver that "in no more than 15 amino acid residues was removed by amendment filed December 19, 2008...claim 1 provides a Factor VII or Factor VIIa polypeptide variant having the modification of L65Q". The instant application does not have such an amendment. The claims were amended on March 26, 2008 and March 30, 2005. The instant application does not have any amendments to the claims dated December 19, 2008 as indicated by applicants. It is noted that the amendment filed on December 19, 2008 makes the

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statement that “the claims have been amended to clarify the language”, however, no claim amendments were contained in that response. The documents in the application can be viewed on public pair to confirm the statements made herein.

The issue remains that the claims encompass several modifications not just the recited L65Q. What has been stated in the office action is that the language “in no more than 15 amino acid residues” introduces new matter and does not obviate the rejection under 35 USC 112, first paragraph with respect to the large genus of Factor VII or Factor VIIa structures. With the open language of “comprising” the language of “in no more than 15” does not limit the number of modifications to 15 in the structure, furthermore, dependent claims are drawn to additional changes. Thus, as the claims have not been amended and the arguments presented on July 28, 2010 are not persuasive the rejections remains.

Conclusion

5. No claims are presently allowable. The mutation L65Q in (SEQ ID NO:1) is free of the art.

6. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652